APR 0 3 2002

GE Medical Systems
General Electric Company
P O Box 414 Milwaukee, WI 53201

K020929

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (262) 544-3894, FAX: (262) 544-3863
Date Prepared: February 8, 2002

PRODUCT IDENTIFICATION

Name: SmartScore 3.5, SmartScore 4.0, SmartScore 4.5

Classification Name: Accessory to Computed Tomography System

Classification Panel 892 - Radiology

Classification Number: 892.1750

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices SmartScore 3.5/4.0/4.5 are substantially equivalent to the device listed below:

Model:	CT Coronary Artery Calcification Scoring (CACS)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K982004

Device Description:
SmartScore 3.5/4.0/4.5 are a family of software options that runs on the Advantage Windows (AW) (K960613) workstation and allows the user to detect calcifications in CT images. These Regions of Interest can be selected manually, or semi-automatically. It provides calculation of the calcium score using multiple scoring algorithms. The software also provides the ability to generate patient reports, and maintain a patient database for future reference.

Indications for Use:
SmartScore 3.5/4.0/4.5 are non-invasive software options that can be used to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease. SmartScore 3.5/4.0/4.5 may be used to monitor the progression/regression of calcium in coronary arteries overtime, which may aid in the prognosis of cardiac disease.

Comparison with Predicate:
SmartScore 3.5/4.0/4.5 are software options that can be used to evaluate calcium scoring in coronary arteries. The functional features of this package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
CT Coronary Artery Calcification Scoring (CACS)	K 982004

Adverse Effects on Health :
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:
SmartScore 3.5/4.0/4.5 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the SmartScore 3.5/4.0/4.5 to be equivalent to those of CT Coronary Artery Calcification Scoring (CACS) (K982004).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 3 2002

GE Medical Systems
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K020929
Trade/Device Name: SmartScore 3.5, SmartScore 4.0, SmartScore 4.5
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: March 18, 2002
Received: March 22, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K020929

Device Name: SmartScore 3.5, SmartScore 4.0, SmartScore 4.5

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020929